K062553

510(k) Summary of Safety and Effectiveness
Simplex™ P Bone Cement

JAN - 8 2007

Proprietary Name:	Simplex™ P Bone Cement
Common Name:	PMMA Bone Cement
Classification Name and Reference	Polymethylmethacrylate (PMMA) bone cement 21 CFR §888.3027
Regulatory Class:	Class II
Device Product Code:	87 LOD - Polymethylmethacrylate (PMMA) bone cement.
Device Manufacturer:	Howmedica International S. de R.L. Raheen Business Park, Limerick, Ireland
For Information contact:	Tiffani Rogers Regulatory Affairs Specialist Stryker Orthopaedics 325 Corporate Drive Mahwah, New Jersey 07432 Phone: (201) 831-5612 Fax: (201) 831-6038 E-Mail: Tiffani.Rogers@stryker.com
Date Summary Prepared:	August 28, 2006

Device Description

Simplex™ P Bone Cement is a radiopaque bone cement capable of being applied digitally and with a syringe. The cement will be available in 10-pack or 1-pack dispensers, with each individual pack containing one 40.0g unit of sterile polymeric powder and one 20.0ml ampoule of sterile monomer, for single-use.

Indications For Use:

Simplex™ P bone cement will be indicated for fixation of prostheses to living bone during orthopaedic musculoskeletal procedures for rheumatoid arthritis, osteoarthritis, traumatic arthritis, osteoporosis, avascular necrosis, collagen disease, severe joint destruction secondary to trauma or other conditions, or revision of a previous arthroplasty. Simplex™ P bone cement is also indicated for the fixation of pathological fractures where loss of bone substance or recalcitrance of the fracture renders more conventional procedures ineffective.

Substantial Equivalence:

The Simplex™ P powder and liquid monomer formula have not been modified and will be the same as what was approved in PMA N17004.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stryker Orthopaedics
% Ms. Tiffani Rogers
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

JAN - 8 2007

Re: K062553
Trade/Device Name: Simplex™ P Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: LOD
Dated: November 13, 2006
Received: November 22, 2006

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Simplex P Bone Cement

Indications

Simplex P bone cement will be indicated for fixation of prostheses to living bone during orthopaedic musculoskeletal procedures for rheumatoid arthritis, osteoarthritis, traumatic arthritis, osteoporosis, avascular necrosis, collagen disease, severe joint destruction secondary to trauma or other conditions, or revision of a previous arthroplasty. Simplex™ P bone cement is also indicated for the fixation of pathological fractures where loss of bone substance or recalcitrance of the fracture renders more conventional procedures ineffective.

Prescription Use ___X___ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(Please Do Not Write Below This Line – Continue on Another Page if Needed)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062553